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FACSIMILE COVER SHEET

Examiner: Leon B. Lankford, Jr. **Group:** 1651

Date: October 4, 2006

Client Code: 2831.2003-000

Facsimile No.: 571-273-8300

From: Mary K. Murray, Ph.D.

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Reg No 47,813

Subject: **Paper:** STATEMENT OF SUBSTANCE OF THE INTERVIEW
Docket No.: 2831.2003-000
Applicants: Tony W. Ho, Gene C. Kopen, William F. Righter, J. Lynn Rutkowski and Joseph Wagner
Serial No.: 09/960,244
Filing Date: September 21, 2001

Number of pages including this cover sheet: 6

Please confirm receipt of facsimile: Yes X No ___

Comments:

iManage;654556;1

@PFDesktop\::ODMA/MHODMA/HBSR05;iManage;652834;1
MKM/bac/(aeg)(bsk)
October 4, 2006

PATENT APPLICATION
Attorney's Docket No.: 2831.2003-000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Tony W. Ho, Gene C. Kopen, William F. Righter, J. Lynn Rutkowski and Joseph Wagner		
Application No.:	09/960,244	Group Art Unit:	1651
Filed:	September 21, 2001	Examiner:	Leon B. Lankford, Jr.
Confirmation No.:	4326		
For:	Cell Populations Which Co-Express CD49c and CD90		

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STATEMENT OF SUBSTANCE OF THE INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Statement of Substance of the Interview is in response to a September 13, 2006 interview with Examiners Leon B. Lankford, Jr., Michael Wityshyn and Interference Practitioner Specialist Cecilia Tsang at the U.S. Patent and Trademark Office. Joseph Wagner, Ph.D., and Gene C. Kopen, Ph.D., Applicants, and Applicants' Attorneys, Mary K. Murray and N. Scott Pierce were present at the interview. Applicants and Applicants' Attorneys thank Examiners Lankford, Wityshyn and Tsang for their helpful suggestions and for granting the interview.

REMARKS

Substance of the Interview

An Interview Summary, dated September 13, 2006, provided Examiner Lankford's summary of the in-person interview conducted on September 13, 2006 between Examiners Lankford, Wityshyn, Tsang and Joseph Wagner, Ph.D. and Gene Kopen, Ph.D., Applicants, and Mary K. Murray and N. Scott Pierce, Applicants' Attorneys.

The substance of the interview concerned suspension of the application in a communication mailed from the U.S. Patent and Trademark Office on February 23, 2006. The suspension of the application followed a Reply to an Office Action made Final, filed on December 13, 2005. Examiner Lankford told Applicants' Attorney, Mary K. Murray, that the period of suspension had expired because U.S. Application No: 10/048,757, filed August 21, 2002 (the '757 Application), issued as U.S. Patent No: 7,015,037 B1 (the '037 Patent) on March 21, 2006. All pending claims were discussed in light of the suspension of the case. Applicants also generally discussed the status of related U.S. Application Nos: 10/251,685 (the '685 Application) and 11/054,824 (the '824 Application) in light of the suspension of the above-referenced case.

Summary of Prosecution and Suspension of Case

A Notice of Allowance and the Fees Due was mailed from the U.S. Patent and Trademark Office on December 15, 2004. The Issue Fee was paid on January 31, 2005. A Notice of Withdrawal From Issue Under 37 C.F.R. § 1.313(b) was mailed from the U.S. Patent and Trademark Office on May 6, 2005. The Notice of Withdrawal From Issue stated that the above-referenced application "was withdrawn from issue after payment of the issue fee for interference" and referenced 37 C.F.R. § 1.313(b)(1).

An Office Action subsequently was mailed from the U.S. Patent and Trademark Office on July 13, 2005. Applicants filed a Reply to the July 13, 2005 Office Action on September 14, 2005. An Office Action Made Final was mailed from the U.S. Patent and Trademark Office on November 30, 2005. On December 13, 2005, Applicants filed a Reply to the Office Action Made Final. A notice of suspension of prosecution was mailed from the U.S. Patent and Trademark Office on February 23, 2006.

Applicants' Attorneys, Mary K. Murray and N. Scott Pierce, thereafter spoke with Examiners Lankford and Wityshyn regarding suspension of the case and requested the in-person interview summarized here.

Summary of the Interview

Applicants and Applicants' Attorneys confirmed with Examiners Wityshyn, Tsang and Lankford that withdrawal of Applicants' case from issue was in light of a request for an interference by the applicants of the '757 Application. Examiner Lankford indicated that suspension of Applicants' application was in the alternative to declaring an interference with the '757 Application. The '757 Application has since issued as U.S. 7,015,037 B1, to Furcht, L.T., *et al.* ("Furcht *et al.*")

Examiner Lankford preliminarily asserted that a Declaration of Robert J. Deans, Ph.D. Under 37 C.F.R. § 1.132 ("Deans Declaration"), filed in support of the Request for Interference by the Furcht *et al.* patent applicants, describes a population of cells prepared by the methods described in WO 01/11011, by Furcht, L.T., *et al.*, which is now the Furcht *et al.* patent. Examiner Lankford further expressed his preliminary opinion that the cell population produced by the method described in the Deans Declaration was Applicants' claimed cell population.

In response, Applicants and Applicants' Attorneys described their claimed invention, which is directed to an isolated cell population derived from human bone marrow, wherein greater than about 91% of the cells of the cell population co-express CD49c and CD90, and wherein in the cell population has a doubling rate of less than about 30 hours. Drs. Wagner and Kopen then summarized the teachings of Furcht *et al.*, stating that, at Col. 15, lines 65-67 of Furcht *et al* , and as shown in Figure 2 therein, Furcht *et al.* teach a population of cells derived from bone marrow that has a doubling time of 36 to 48 hours for an initial 20 to 30 cell doublings and, afterward, a cell doubling time of 60-72 hours. Drs. Wagner and Kopen, in addition, noted that Furcht *et al.* teach a cell population derived from bone marrow that has a doubling time of 48-60 hours, and stains positive for antibodies directed to, *inter alia*, CD90 (Col. 45, lines 42-51 of Furcht *et al.*). Applicants' Attorneys, Murray and Pierce, reiterated the argument already of record in the prosecution history of Applicant's suspended application, namely, that Furcht *et al.* do not disclose, explicitly or inherently, or suggest, an isolated cell

population derived from human bone marrow, having a population doubling time of less than about 30 hours and wherein greater than about 91% of the cells in the isolated cell population co-express CD49c and CD90, as claimed in Applicants' suspended application. Further, and contrary to Examiner Lankford's preliminary statements at the interview, Drs. Wagner and Kopen asserted that the experimental methods employed in the Deans Declaration are not described in Furcht *et al.* or in any of the applications to which Furcht *et al.* claims priority or the benefit.

In addition, Drs. Wagner and Kopen pointed out that, contrary to statements made on pages 4 and 7 of the Deans Declaration, Figures 2 and 4, on pages 11 and 13 of the Deans Declaration, do not necessarily depict a population of cells where at least about 91% of the cells of the cell population co-express CD49c and CD90. Rather, Figures 2 and 4 of the Deans Declaration depict expression of CD49c (upper right frame) and CD90 (lower right frame) on the surface of cells; separate measurements of expression of CD49c and CD90 are not necessarily a measurement of co-expression of these factors. In particular, where 91% of the cells express CD49c and, separately, 91% of the cells express CD90, co-expression of these factors may be as low as 83% (0.91 x 0.91 = 0.83). Further, Drs. Wagner and Kopen stated that, contrary to the statement on pages 4 and 7 of the Deans Declaration, Figures 1 and 3, on pages 10 and 12 of the Deans Declaration, depict cell doublings (CD) and not cell doubling rate (number of days in culture x 24 hours/doubling). They further stated that, moreover, the cell doubling rates, calculated from the cell doubling of Figures 1 and 3, generally are in excess of 30 hours, and those of Figure 3 are all well in excess of 30 hours.

Applicants and Applicants' Attorneys summarized that, despite statements made in the Deans Declaration and referenced by Examiner Lankford during the interview, Furcht *et al.* do not describe, expressly or inherently, or suggest, a cell population wherein greater than 91% of the cells co-express CD49c and CD90 and wherein the cell doubling rate is less than about 30 hours.

SUMMARY CONCLUSION

The cell populations purported by the Deans Declaration in the file history of Furcht *et al.* are not, expressly or inherently, Applicants' claimed cell population. Therefore, Applicants' claimed invention meets the requirements of 35 U.S.C. § 102(e) in light of Furcht *et al.*

Applicants respectfully request reconsideration and allowance of Claims 14, 19-21, 25 and 26. If the Examiner feels a telephone conference would expedite prosecution of this application, he is invited to call Applicants undersigned Attorney.

Respectfully submitted,

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Dated: October 4, 2006